

REMARKS

The Examiner's attention is directed to the accompanying petition submitted under 37 C.F.R. 1.103(a); the petition requests suspension of action in the present application. A decision on this petition is requested prior to examination and issuance of a first Office Action. Further, if the declaration to be submitted prior to May 17, 1998 has not reached the Examiner when this application is taken up for examination, she is invited to contact the undersigned.

Claims 4-10 and 22-23 are pending. New claims 22-23 are directed to GDF-1 protein lacking a signal peptide as shown by *in vitro* translation of full-length GDF-1 transcript in the presence of dog pancreas microsomes (Example 2).

The amendments to the claims find support throughout the original disclosure and, thus, do not introduce new matter. See, in particular, pages 20-22 of the specification.

Claims 4-10 were rejected under 35 U.S.C. 112, first paragraph, as allegedly "containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention". Applicant traverses.

Contrary to the statement on pages 2-3 of the Office Action (Paper No. 4), applicant does not agree with the Examiner that uses of the claimed invention discussed in the

previous Office Action are not enabled. Applicant is not arguing that a person skilled in the art would have to "dream up" potential uses of the present invention. Instead, applicant submits that the Examiner has not explained in previous Office Actions why the objective truth contained in the disclosure is doubted by "evidence or reasoning which is inconsistent with the contested statement". M.P.E.P. 2164.01 and *In re Marzocchi*, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971). No such evidence or reasoning was given in the previous Office Actions, the Examiner merely stated her belief that "it could not be predicted which activity GDF-1 would have, if any" (page 2 of Paper No. 3). Thus, the Examiner's objection appears to be based on the lack of working examples in the specification. However, applicant submits that working examples are not required in order to comply with Section 112, first paragraph, (M.P.E.P. 2164.02) especially in view of the other examples provided in the specification.

Although applicant maintains that this is sufficient to overcome the Examiner's objection to the specification, a declaration is being prepared to further prosecution in the present application. As discussed in the petition, suspension is requested to allow applicant time to prepare a declaration containing evidence responsive to the pending enablement rejection. Such declaration evidence should be further considered as a response to the pending enablement rejection.

LEE - FWC of Appln. No. 08/607,485

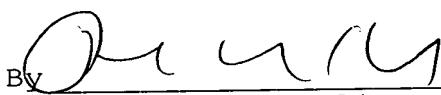
Finally, it is noted that the Hoben et al. reference supports the use of GDF-1 as a lineage marker because of its expression "primarily in the nervous system". Further, the cited abstract does not support the Examiner's allegation that "biological activity, and assays therefore, for GDF-1 had not been determined at the time of the invention" (page 5 of the Office Action, Paper No. 4). Instead the abstract describes further characterization of GDF-1 and studies showing that recombinant GDF-1 "stimulates the expression of the immediate early genes in neural cell lines". Thus, one would not conclude from the abstract that GDF-1 does not have a biological activity or that such activities as disclosed in the present application are incredible.

A favorable action on the merits is earnestly requested. If any further information is required, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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